REMARKS

Reconsideration is requested.

The specification has been amended to include a cross-reference to the parent PCT application. No new matter has been added.

The applicants elect, with traverse, the subject matter of the Examiner's Group I for further prosecution in the above. The applicants further elect, with traverse, the sequence of SEQ ID NO:2.

Reconsideration and withdrawal of the restriction requirements are requested for any of the following reasons.

The Examiner is urged to appreciate that the present application is a 371 U.S. national phase of PCT/GB99/01387. Accordingly, the principles of unity of invention apply. The applicants respectfully submit that the Examiner has failed to establish that the claims do not define a special technical feature, such as by demonstrating that the subject matter of the Examiner's Groups I and II fail to define a contribution, as a whole, over the prior art. See, Annex B of the PCT Administrative Instructions.

Specifically, MPEP § 1850 states as follows, in relevant part (emphasis added):

> 37 CFR 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.
>
> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall

mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

.....

THE REQUIREMENT FOR "UNITY OF INVENTION"

Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.

The decision in Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks, 231 USPQ 590 (E.D. Va. 1986) held that the Patent and Trademark Office interpretation of 37 CFR 1.141(b)(2) as applied to unity of invention determinations in international applications was not in accordance with the Patent Cooperation Treaty and its implementing regulations. In the Caterpillar international application, the USPTO acting as an International Searching Authority, had held lack of unity of invention between a set of claims directed to a process for forming a sprocket and a set of claims drawn to an apparatus (die) for forging a sprocket. The court stated that it was an unreasonable interpretation to say that the expression "specifically designed" as found in former PCT Rule 13.2(ii) means that the process and apparatus have unity of invention if they can only be used with each other, as was set forth in MPEP § 806.05(e).

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, **PCT Rule 13.1 and 13.2 will b followed when considering unity of invention of claims of different categories without regard to the practice in national applicati ns filed under 35 U.S.C. 111.** No change was

made in restriction practice in United States national applications filed under 35 U.S.C. 111 outside the PCT.

In applying PCT Rule 13.2 to international applications as an International Searching Authority, an International Preliminary Examining Authority and to national stage applications under 35 U.S.C. 371, examiners **should** consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

PCT Rule 13.2, as it was modified effective July 1, 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

A. Independent and Dependent Claims

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a

dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

...

PCT Rule 13.3 requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

PCT Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in PCT Rule 13.2) remains the same regardless of the form of claim used.

PCT Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority or Office.

The Examiner has asserted that the subject matter of the Examiner's Groups I and II are separately patentable because "the product of group II does not share the special technical feature [separately alleged by the Examiner to be "a vaccine comprising a vector encoding an attenuated sequence of VEE and a first method of use"] because it is a second product comprising additional ingredients that are outside of the defining special technical feature of group I." See, page 2 of the Office Action dated October 3, 2003 (Paper No. 5).

Claim 18, which defines the Examiner's Group II, provides "A multivalent vaccine comprising a vaccine according to claim 1 and a further vaccine." The subject matter of the Examiner's Group II therefore includes all of the details of the subject matter of the Examiner's Group I, as defined by claims 1-17. The subject matter of the Examiner's Group II therefore includes the same special technical feature as the subject matter of the Examiner's Group I. As noted above, the Examiner has failed to demonstrate that the independent claims are found in the prior art. As explained above from the quoted passage of the MPEP, if the independent claims avoid the prior art and satisfy the requirement for unity of invention, "no problem of lack of unity arises in respect of any claims that depend on the independent claims."

In support of the applicants belief that unity of invention exists as between the subject matter of the Examiner's Groups I and II, the Examiner is urged to appreciate that the European Patent Office, acting as the Preliminary Searching Authority, did not find a lack of unity of invention. See, the International Preliminary Examination Report

mailed November 2, 2000, which should be contained in the file of the U.S. Patent Office. A further copy will be forwarded upon the Examiner's request for the same.

Accordingly, in view of all of the above, the restriction requirement as between the Examiner's Groups I and II should be withdrawn.

The Examiner is further requested to withdraw the restriction requirement relating to the election of either SEQ ID NO:2 or SEQ ID NO:3. Consideration of the following in this regard is requested.

The Examiner asserts the restriction requirement as between SEQ ID NO:2 and SEQ ID NO:3 is required as, apparently, the Examiner believes these sequences also lack a unity of invention. The Examiner has only asserted however that restriction is proper as "each of the sequences is structurally distinct, as evidenced by a separately designated sequence identifier." See, page 2 of Paper No. 5.

Initially, the applicants note that SEQ ID NO:2 and SEQ ID NO:3 are each 33 bases in length and differ by a single base (i.e., at position 16). The sequences of SEQ ID NOs: 2 and 3 could have been defined by a single SEQ ID NO. The fact that the sequences, which differ by a single base, are defined as separate SEQ ID NOs:, is not an appropriate basis for finding a lack of unity of invention and requiring a restriction between the two sequences.

The Examiner will appreciate that SEQ ID NO:2 and SEQ ID NO:3 define alternative promoter sequences which are recited in dependent claim 8, as alternate embodiments of the promoter of claim 7, which has been found to increase the level of VEE virus protein production as compared to wild-type 7.5 K promoter. The vaccine of dependent claim 7 is an alternate embodiment of dependent claim 6, which provides a

vaccine of dependent claim 5, containing an attenuated vaccinia virus. The vaccine of dependent claim 5 provides an alternate embodiment of the vaccine of dependent claim 3, which provides an alternate embodiment of the vaccine of claim 2, which in turn provides an alternate embodiment of the vaccine of independent claim 1.

The special technical feature of claim 1 is contained in the dependent claim 8, which additionally includes the recitation of specific promoter sequences SEQ ID NO:2 and SEQ ID NO:3.

The Examiner's basis for requiring of an election as between SEQ ID NO:2 and SEQ ID NO:3 appears to be similar to restriction requirements made in U.S. applications which do not derive from PCT applications. The Examiner is urged to appreciate however that even with regard to the SEQ ID NOs: 2 and 3, the Examiner must demonstrate that a lack of unity of invention exists in order to maintain the restriction requirement. Specifically, the Examiner is requested to see again the above-quoted sections of the MPEP which state, in relevant part, the following:

> **LACK OF UNITY OF INVENTION**
> **See Annex B of the Administrative Instructions for examples of unity of invention.**
>
> UNITY OF INVENTION - NUCLEOTIDE SEQUENCES
>
> Under 37 CFR 1.475 and 1.499 et seq., when claims do not comply with the requirement of unity of invention, i.e., when the claimed subject matter does not involve "one or more of the same or corresponding special technical features," 37 CFR 1.475(a), an additional fee is required to maintain the claims in the same application. 37 CFR 1.476 (b).

> The Commissioner has decided sua sponte to partially waive 37 CFR 1.475 and 1.499 et seq. to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature without the payment of an additional fee. The PCT permits inventions that lack unity of invention to be maintained in the same international application for payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the USPTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.
>
> See MPEP § 803.04 for examples of nucleotide sequence claims impacted by this partial waiver of 37 CFR 1.475 and 1.499 et seq.

MPEP § 803.04 states as follows, in relevant part (emphasis added):

> By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).
>
> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the

biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

See MPEP § 1850 for treatment of claims containing independent and distinct nucleotide sequences in international applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. 371.

EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS

Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include:

(A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;

(B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and

(C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all

> combinations containing the allowed sequence(s) to be allowed.
>
> In applications containing all three claims set forth in examples (A)-(C), the Office will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example (A), all combinations, such as in examples (B) and (C), containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.
>
> Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and nonselected and which are limited to the allowable sequence(s) will be rejoined and examined.

The whole of MPEP § 803.04 therefore appears to relate to restriction of nucleotide sequences in applications other than U.S. national phase of PCT applications and appears to describe a partial waiver of the Commissioner's determination that each nucleotide sequence is an independent and distinct invention which define, in regular U.S. utility applications (i.e., non-U.S. national phase applications of PCT applications) a separately patentable invention. Without the partial waiver of MPEP § 803.04, the Commissioner could require that each nucleotide sequence be pursued in separate divisional patent applications. The partial waiver MPEP § 803.04 permits a "reasonable number" of nucleotide sequences, indicated as "normally ten sequences", to be claimed in a single application. It has been the undersigned's experience that, in practice, this "waiver" is itself waived and the Patent Office requires restriction and examination of a single nucleotide sequence per application.

The Examiner is urged to appreciate that 37 CFR §§ 1.142(a) and 1.141(a) referred to in MPEP § 803.04 relate to the "independent and distinct" standard of restriction practice of U.S. utility applications, as opposed to the principles of unity of invention applied to U.S. national phase applications of PCT applications, such as the above-identified application, pursuant to 37 CFR § 1.499. The Examiner is further urged to appreciate that 37 CFR § 1.499 provides as follows:

> 37 CFR § 1.499 Unity of invention during the national stage.
>
> If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

The only reference in MPEP § 803.04 to treatment of U.S. national phase applications of PCT applications are (a) a general direction to see MPEP § 1850, and (b) an example of claim types (generally dealing with large numbers of nucleotide sequences) impacted by the partial waiver of 37 CFR § 1.499, as described in MPEP § 1850.

The claims of the present application are not believed to be characterized by the Example claim types (A)-(C) reproduced above from MPEP § 803.04 such that the requirement for the Patent Office to examine ten sequences in this specific situation is not believed to be applicable to the present application. The Examiner however is requested to advise the applicants if otherwise.

Accordingly, MPEP § 803.04 instructs review of MPEP § 1850 for "treatment of claims containing independent and distinct nucleotide sequences ... in national stage applications filed under 35 U.S.C. 371."

MPEP § 1850 states, with reference to the specific treatment of UNITY OF INVENTION - NUCLEOTIDE SEQUENCES and the "waiver" of MPEP § 803.04, that the threshold issue of unity of invention, i.e., finding that the claimed subject matter does not involve one or more of the same or corresponding special technical features, is still required and that if unity is not found in cases claiming nucleotide sequences, the Commissioner will allow examination of up to ten sequences without payment of additional fees. The reference in MPEP § 1850 to payment of additional fees is believed to be a reference to international applications where the USPTO is acting as the international preliminary examining authority, as opposed to any requirement relating to U.S. national phase (i.e., 37 CFR § 1.371) applications.

More importantly, unlike the statements in MPEP § 803.04 relating to treatment of nucleotide sequences in U.S. utility applications which are "deemed" to each define independent and distinct inventions, MPEP § 1850 does not similarly sua sponte define nucleotide sequences as lacking unity of invention. Accordingly, MPEP § 1805 is believed to require the Patent Office, even in the case of claims to and involving nucleotide sequences, to establish a lack of unity of invention to justify a restriction requirement.

The Examiner is requested to either demonstrate that SEQ ID NOs: 2 and 3 do not share the same or a corresponding special technical feature, as described, for

example, in MPEP § 1850, or withdraw the restriction requirement and examine all the pending claimed subject matter.

The Examiner in the above has not demonstrated that the pending claims do not share the same or corresponding special technical feature, as described in MPEP § 1850, and the restriction requirement of October 3, 2003, therefore should be withdrawn, and all the claims examined on the merits.

The Examiner is requested to contact the undersigned in the event anything further is required for responding to the Office Action of October 3, 2003.

Respectfully submitted,

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By: _____

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